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Published by Elsevier Science Inc.
ISSN 0735-1097/02/$22.00
PII S0735-1097(02)02605-0

Gender-Related Changes in the Practice and Outcomes of Percutaneous Coronary Interventions in Northern New England From 1994 to 1999

David J. Malenka, MD,*‡ David E. Wennberg, MD, MPH,§‖ Hebe A. Quinton, MS,† Daniel J. O'Rourke, MD, MS,* Paul D. McGrath, MD, MS,§‖ Samuel J. Shubrooks, Jr, MD,¶ Gerry T. O'Connor, PhD, DSc,†‡ Thomas J. Ryan, Jr, MD,‖ John F. Robb, MD,* Mirle A. Kellett, Jr, MD,‖ William A. Bradley, MD,# Michael A. Hearne, MD,# Peter N. VerLee, MD,** Matthew W. Watkins, MD,†† Bruce D. Hettleman, MD,* Winthrop D. Piper, MSc,† for the Northern New England Cardiovascular Disease Study Group

Lebanon, Hanover, and Manchester, New Hampshire; Portland and Bangor, Maine; Boston, Massachusetts; and Burlington, Vermont

OBJECTIVES We sought to determine whether the changing practice of interventional cardiology has been associated with improved outcomes for women, and how these outcomes compare with those for men.

BACKGROUND Previous work from the early 1990s suggested women are at a higher risk than men for adverse outcomes after percutaneous coronary interventions (PCIs).

METHODS From 1994 to 1999 data were collected on 33,666 consecutive hospital admissions for a PCI in Northern New England. Multivariate models were used to adjust for differences in case-mix across year of procedure when comparing outcomes. Direct standardization was used to calculate adjusted rates.

RESULTS From 1994 to 1999, the case-mix worsened for both women and men, although women had more co-morbidities than did men throughout the period. Stent use increased over time (>75% in 1999). Concomitantly, the need for emergency coronary artery bypass graft surgery (CABG) decreased significantly ($p_{trend} \leq 0.001$; in 1999: 0.06% for women, 0.05% for men). Although the emergency CABG rates were higher for women at the beginning of the study, by the end, they were comparable (adjusted odds ratio 1.34, 95% confidence interval 0.76 to 2.38, $p = 0.315$). The myocardial infarction (MI) rates decreased over time for both women (by 29.7%, $p_{trend} = 0.378$) and men (by 37.6%, $p_{trend} = 0.009$) and did not differ by gender. The mortality rates did not decrease significantly over time and were not significantly different between the genders (mean 1.21% for women, 1.06% for men; $p = 0.096$).

CONCLUSIONS Concurrent with the changing practice of PCI, and despite treating sicker patients, there have been important improvements in post-PCI CABG and MI rates for women, as well as for men. Unlike in earlier years, there are no longer significant differences in outcomes by gender. (J Am Coll Cardiol 2002;40:2092–101) © 2002 by the American College of Cardiology Foundation

Women undergoing a percutaneous coronary intervention (PCI) may face a higher risk of adverse outcomes than do men. This was our experience in Northern New England in the early 1990s, when we reported (1) a higher risk of in-hospital death after PCI for women than for men (odds ratio [OR] 1.64, 95% confidence interval [CI] 1.09 to 2.47). Although the published data on this topic are discrepant (2–11), there is reason to suspect that outcomes could be worse for women than for men. A number of studies suggest that women undergo PCIs later in the course of their disease, present with more co-morbidities, and have a more technically difficult anatomy to revascularize (12–18).

Most studies reporting on the process and outcomes of PCI for women versus men date from the early to mid-1990s. Since that time, the practice of interventional cardiology has changed (19). Catheters have been improved; they have better compliance characteristics and lower profiles and allow for perfusion distal to the balloon. Alternative devices for lesion-specific treatment are available. Coronary stents for "bail-out" in the setting of abrupt closure or suboptimal results are widely used, and the advent of high-pressure inflation and intravascular ultrasound has lowered the associated risk of acute thrombus formation. Clinical trials and ever-growing experience have taught cardiologists more about case selection and the use of adjunctive medical therapy, particularly platelet glycoprotein (GP) IIb/IIIa receptor inhibitors. Given all these changes, the outcomes for women after PCI may be improving. To determine whether this is true, we examined our 1994–1999 Northern New England PCI registry data to characterize the current

From the *Section of Cardiology, Dartmouth-Hitchcock Medical Center, Lebanon, New Hampshire; †Clinical Research Section, Department of Medicine, and ‡Center for Evaluative and Clinical Sciences, Dartmouth Medical School, Hanover, New Hampshire; §Division of Health Services Research and ‖Division of Cardiology, Department of Medicine, Maine Medical Center, Portland, Maine; ¶Division of Cardiology, Beth Israel Deaconess Medical Center, Boston, Massachusetts; #Catholic Medical Center, Manchester, New Hampshire; **Eastern Maine Medical Center, Bangor, Maine; and ††Division of Cardiology, Fletcher Allen Health Care, Burlington, Vermont.

Manuscript received February 22, 2002; revised manuscript received June 20, 2002, accepted July 15, 2002.

Abbreviations and Acronyms

BSA	= body surface area
CABG	= coronary artery bypass graft surgery
CHF	= congestive heart failure
COPD	= chronic obstructive pulmonary disease
DM	= diabetes mellitus
GP	= glycoprotein
LMCA	= left main coronary artery
PCI	= percutaneous coronary intervention
LVEDP	= left ventricular end-diastolic pressure
MI	= myocardial infraction

practice of interventional cardiology in women, to compare it to past practice, and to contrast it to the experience of men.

METHODS

The Northern New England Cardiovascular Disease Study Group is a voluntary research consortium composed of clinicians, research scientists, and hospital administrators at five institutions in Maine, New Hampshire, and Vermont, which are providers of coronary revascularization in the region, as well as one Massachusetts-based institution. The intent of the group is to foster continuous improvement in the quality of care of patients with cardiovascular disease in Northern New England by pooling process and outcome data and its timely feedback to clinicians (20,21).

Between January 1, 1994 and December 31, 1999, data were collected on 33,666 consecutive hospital admissions (10,977 [32.6%] women and 22,689 [67.4%] men) during which PCI was performed. Information was collected in the following categories: demographics; medical history; primary indication for PCI; priority at PCI; therapy before, during, and after the procedure; cardiac anatomy and function; procedural information; and in-hospital outcomes, including death, emergency coronary artery bypass graft surgery (CABG), nonemergency CABG, or new myocardial infarction (MI), defined as chest pain, diaphoresis, dyspnea, and/or hypotension associated with the development of new Q waves or ST-TW–segment changes and a rise in creatine kinase (CK) to at least twice the normal value, with a positive CK-MB fraction. Clinical success was defined as one or more attempted lesion(s) successfully dilated and no adverse clinical outcomes. Adverse clinical outcomes included any hospital death, emergency or nonemergency CABG, or postprocedural MI. The failure to cross or engage at least one lesion was not considered an adverse clinical outcome but would prevent a procedure from being labeled a clinical success.

The number of patients in the data set was verified using hospital discharge data supplemented by cardiac catheterization laboratory logs. Information was obtained for any missing procedure. The outcomes of death and CABG were validated from the hospital discharge data set and a review of the medical records through 1998. Myocardial infarction was validated only for 1994 by a review of the medical records.

All analyses were carried out using Statistical Analysis Software, release 6.11 (SAS, Cary, North Carolina) or STATA Statistical Software, release 5.0 (Stata Corp, College Station, Texas). For the purpose of analysis, the registry experience was divided into three eras based on an examination of changing practice patterns in the use of stents within the region (Fig. 1A) and our knowledge of how the indication for stenting changed over time: 1994 to June 1995 = early stent experience; July 1995 to 1997 = provisional stenting experience; 1998 to 1999 = current stent experience. Logistic regression (22) was used to assess whether changes in case-mix and outcomes differed over time, reported as p_{trend}, except for the ordinal variables of indication, priority, and lesion type, where the Mantel-Haenszel chi-squared statistic was used. The p value for trend is useful for detecting any linear relationship between exposure and disease. Multivariate models were used to adjust for differences in case-mix and severity of illness across year of procedure when comparing outcomes. All variables demonstrating a univariate association with the dependent variable of interest at $p < 0.10$ were considered potential independent variables for inclusion in the multivariate analyses. To determine whether there was a significant change in outcomes over time, a variable for year of procedure was forced into the multivariate model. Direct standardization (23) was used to calculate adjusted rates. Comparisons of outcomes in women versus men are reported as ORs, with men as the referent group, calculated using standard statistical methods (24), with 95% CIs.

RESULTS

The average age of women undergoing PCI increased by 0.6 years during the mid-1990s, with a slight increase in those ≥80 years old in 1998 to 1999 (Table 1). In addition, the prevalence of vascular disease, renal failure, previous CABG, congestive heart failure (CHF), ejection fraction <40%, left ventricular end-diastolic pressure (LVEDP) >18 mm Hg, and significant left main coronary artery (LMCA) disease all increased. The prevalence of cigarette smoking decreased, although it remained high at 24.3% in 1998–1999, as did the prevalence of previous MI, previous PCI, and multivessel coronary artery disease. Average body surface area (BSA), creatinine, diabetes mellitus (DM), and chronic obstructive pulmonary disease (COPD) all remained relatively stable (<1% change) over time. In men, the average age increased by two years over time, with an increase of 1.1% in those ≥80 years old. The prevalence of DM, vascular disease, COPD, renal failure, previous CABG, CHF, ejection fraction <40%, LVEDP >18 mm Hg, and LMCA disease increased over the study period, whereas the other patient characteristics remained relatively stable. Compared with men, women were approximately five to six years older at the time of their PCI, and there

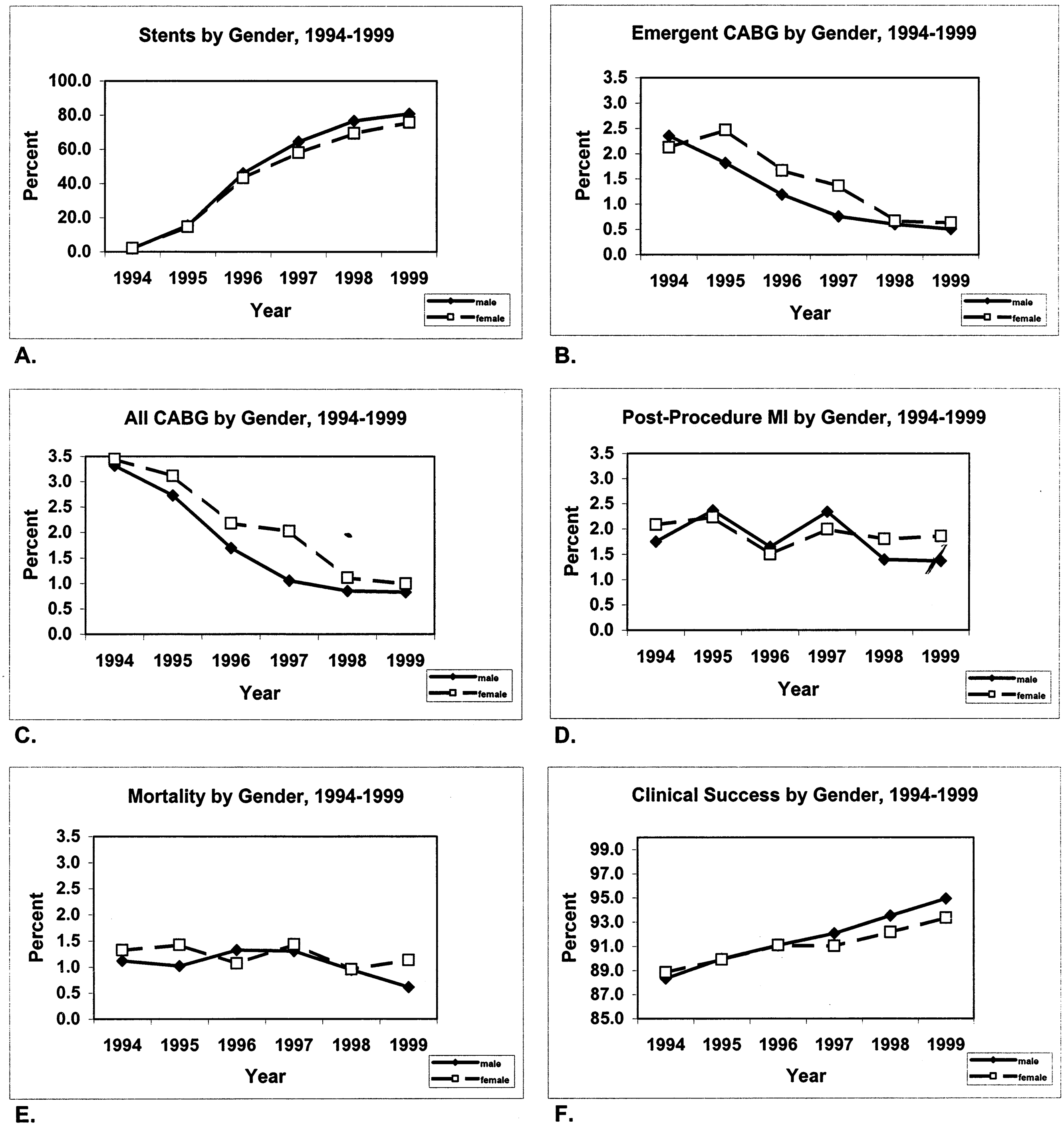

Figure 1. **(A to F)** Changing risk-adjusted in-hospital outcomes for women and men undergoing percutaneous coronary intervention (PCI) in Northern New England from 1994 to 1999. CABG = coronary artery bypass graft surgery; MI = myocardial infarction.

were more women ≥80 years old. As expected, women were smaller than men and had lower creatinine levels. Women had more DM, vascular disease, COPD, renal failure, and CHF and were more likely to have LVEDP >18 mm Hg, as compared with men. Women were less likely to smoke and have a history of MI, previous PCI, previous CABG, and LMCA and three-vessel disease.

In women, procedural indications and priority (Table 2) remained relatively stable over time, with the exception of a small decrease in unstable angina and an increase in stable angina and primary PCI for MI, the last of which was accompanied by an increase in emergent procedures. Even in more recent years, <10% of procedures in women involved more than one lesion, although lesion complexity increased, with a higher percentage of lesions being classified as American College of Cardiology (ACC) type B2 and

Table 1. Clinical Characteristics of Women and Men Undergoing a PCI in Northern New England by Era of Stenting

Characteristic	Stent Era: Early (1994–6/95)	Stent Era: Provisional (7/95–1997)	Stent Era: Current (1998–1999)	p_{trend}*
Women (n)	2,310	4,684	3,983	
Men (n)	4,879	9,753	8,057	
Mean age (yrs)				
Women	65.3	65.9	65.9	< 0.001
Men	59.3	60.1	61.3	< 0.001
Age ≥ 80 yrs (%)				
Women	9.5	9.9	11.4	< 0.001
Men	3.8	4.1	4.9	< 0.001
Mean BSA (m^2)				
Women	1.85	1.84	1.82	< 0.001
Men	2.00	2.03	2.06	< 0.001
Mean creatinine (mg/dl)				
Women	1.0	1.0	1.0	0.551
Men	1.1	1.1	1.1	< 0.001
Co-morbidities (%)				
Smoker				
Women	27.2	26.1	24.3	< 0.001
Men	31.9	36.0	32.7	< 0.001
Diabetes mellitus				
Women	29.1	28.9	29.8	0.824
Men	17.8	19.3	20.7	< 0.001
Vascular disease				
Women	12.1	12.4	14.8	< 0.001
Men	8.7	9.5	11.6	< 0.001
COPD				
Women	10.1	10.5	10.9	< 0.001
Men	8.3	8.6	9.2	< 0.001
Renal failure				
Women	1.6	3.0	4.8	< 0.001
Men	1.4	2.5	4.2	< 0.001
Previous cardiac history (%)				
Previous MI				
Women	23.1	20.8	19.5	< 0.001
Men	28.0	24.8	23.3	< 0.001
Previous PCI				
Women	27.8	25.0	24.4	0.011
Men	31.8	26.0	26.6	< 0.001
Previous CABG				
Women	11.3	12.7	13.5	< 0.001
Men	14.2	16.7	18.7	< 0.001
Congestive heart failure				
Women	6.0	9.5	12.2	< 0.001
Men	3.9	6.0	7.4	< 0.001
Cardiac anatomy and function (%)				
Ejection fraction <40%				
Women	3.7	4.8	5.7	0.336
Men	4.0	5.9	6.5	< 0.001
LVEDP >18 mm Hg				
Women	14.8	14.3	16.6	0.079
Men	12.2	12.3	13.8	0.344
≥50% LMCA disease				
Women	1.6	2.8	3.6	< 0.001
Men	2.4	4.1	5.1	< 0.001
Multivessel disease				
Women	33.8	31.0	31.5	< 0.001
Men	36.4	33.7	36.8	< 0.001

*Analysis of variance for continuous variables.

BSA = body surface area; CABG = coronary artery bypass graft surgery; COPD = chronic obstructive pulmonary disease; LMCA = left main coronary artery; LVEDP = left ventricular end-diastolic pressure; MI = myocardial infarction; PCI = percutaneous coronary intervention.

Table 2. Indication, Priority, and Procedural Characteristics of Women and Men Undergoing a PCI in Northern New England by Era of Stenting

Characteristic	Stent Era			p_{trend}
	Early (1994–6/95)	Provisional (7/95–1997)	Current (1998–1999)	
Women (n)	2,310	4,684	3,983	
Men (n)	4,879	9,753	8,057	
Indication for first procedure (%)				
Women				
Stable angina	19.3	18.2	20.9	0.020
Unstable angina	74.3	75.6	71.6	
Primary therapy for MI	3.7	4.2	5.4	
Cardiogenic shock	0.4	0.8	1.1	
Other	2.3	1.2	1.1	
Men				
Stable angina	23.8	24.4	26.2	< 0.001
Unstable angina	68.6	68.5	65.6	
Primary therapy for MI	4.4	5.6	6.8	
Cardiogenic shock	0.6	0.5	0.6	
Other	2.6	0.9	0.8	
Priority for first procedure (%)				
Women				
Emergent	8.3	7.9	9.3	0.086
Urgent	61.0	60.7	61.8	
Nonurgent	30.7	31.4	28.9	
Men				
Emergent	9.3	9.2	10.0	< 0.001
Urgent	53.2	54.5	56.8	
Nonurgent	37.6	36.3	33.2	
Lesion characteristics (%)				
>2 lesions attempted				
Women	7.4	7.8	8.2	< 0.001
Men	6.9	7.8	10.0	< 0.001
Proximal LAD attempted				
Women	17.8	17.3	17.1	0.072
Men	17.6	16.6	15.3	< 0.001
Graft attempted				
Women	5.0	3.8	5.5	< 0.001
Men	5.6	7.1	7.8	< 0.001
Lesions types				
Women				
A	42.5	29.8	20.0	< 0.001
B1	38.8	39.2	40.6	
B2	11.4	22.3	28.3	
C	7.3	8.8	11.2	
Men				
A	38.5	28.0	17.7	< 0.001
B1	40.9	39.9	40.4	
B2	12.2	22.7	29.5	
C	8.4	9.4	12.4	
Devices (%)				
Stent				
Women	3.9	45.8	72.4	< 0.001
Men	4.1	49.7	78.6	< 0.001
Directional atherectomy				
Women	7.8	2.0	1.5	< 0.001
Men	10.3	3.6	1.7	< 0.001
Rotational atherectomy				
Women	4.1	7.6	10.7	< 0.001
Men	3.3	5.4	7.7	< 0.001
Glycoprotein IIb/IIIa inhibitors (%)				
Women	0	7.2	20.3	< 0.001
Men	0.1	8.8	22.8	< 0.001

LAD = left anterior descending coronary artery; MI = myocardial infarction; PCI = percutaneous coronary intervention.

Table 3. Unadjusted Rates of In-Hospital Outcomes of Women and Men Undergoing a PCI in Northern New England by Era of Stenting

In-Hospital Outcome	Stent Era: Early (1994–6/95)	Stent Era: Provisional (7/95–1997)	Stent Era: Current (1998–1999)	p_{trend}
Clinical success (%)				
Women	89.22	91.12	92.49	< 0.001
Men	89.28	91.68	94.05	< 0.001
MI (%)				
Women	2.34	1.75	1.93	0.005
Men	1.93	2.05	1.39	0.002
Any CABG (%)				
Women	3.55	2.16	1.06	< 0.001
Men	3.20	1.56	0.82	< 0.001
Emergent CABG				
Women	2.38	1.60	0.63	< 0.001
Men	2.21	1.09	0.55	< 0.001
Nonemergent CABG				
Women	1.17	0.56	0.43	< 0.001
Men	0.98	0.47	0.27	< 0.001
Death (%)				
Women	1.47	1.54	1.43	0.568
Men	0.94	1.06	0.79	0.453

CABG = coronary artery bypass graft surgery; PCI = percutaneous coronary intervention.

C in more recent years. The biggest procedure-related change over time in women was in the use of devices and GP IIb/IIIa inhibitors. There was a marked increase in the use of stents (Fig. 1A), such that by 1999, 75.9% of women undergoing PCI received one or more stent(s). Although directional atherectomy was rarely used in recent years, rotational atherectomy use increased to 10.7% in 1998 to 1999. The use of GP IIb/IIIa inhibitors was largely confined to more recent years, and they were used selectively in 20.3% of patients. The temporal changes seen over time in women were largely parallel to those in men. However, compared with men, women were more likely to present with unstable angina, require an urgent procedure, undergo rotational atherectomy, or have an intervention on a proximal left anterior descending coronary lesion, and they were less likely to undergo a graft PCI, have a stent placed, or receive a GP IIb/IIIa inhibitor. There was no gender-related difference in stent use after controlling for patient age and BSA (OR 1.04, 95% CI 0.99 to 1.08).

Procedural outcomes, both unadjusted and adjusted, are summarized in Tables 3 and 4, respectively (by era of stenting), and are shown by year in Figure 1 to help clarify trends. Controlling for differences in case-mix over time made little difference in the point estimates of most outcomes, except for in-hospital mortality. When not specified, we refer to adjusted rates. In women, there was a clinically important and statistically significant decrease in the rates of emergency and nonemergency CABG during the 1990s. The overall CABG rate decreased by 72.3% for women ($p_{trend} < 0.001$), with an absolute decrease of 2.45%. The MI rates decreased by 27.7% from the periods 1994 to June 1995 and July 1995 to 1997 and then leveled off ($p_{trend} < 0.378$). There was not a significant trend toward a lower postprocedural in-hospital mortality rate during the study period (average mortality 1.21%; $p_{trend} < 0.846$), although mortality in the current era of stenting was 20% lower than that in the era of provisional stenting. As a consequence, largely due to decreased rates of CABG and MI and a small decline in the inability to cross or engage lesions, clinical success rates improved by 4.41% during the second half of the decade, reaching 93.45% ($p_{trend} < 0.001$) in the period 1998 to 1999.

The CABG rates for men in this period decreased by 75% ($p_{trend} < 0.001$), with an absolute decrease of 2.49%. The MI rates remained stable until 1998 to 1999, when they decreased by 35% to 1.36% in 1998 to 1999 ($p_{trend} < 0.001$). Compared with women, the mortality rates for men remained relatively constant in the eras of early and provisional stenting, decreasing by 37.5% only in the current era of stenting (average mortality 1.06%; $p_{trend} < 0.273$). Mainly because of a combined decrease in CABG and MI rates, as well as a decrease in the inability to cross or engage lesions, the clinical success rate for men increased by 5.95% to 94.2% in 1998 to 1999.

For most of the study period, the CABG rates in women were slightly higher than those in men, driven by differences in the need for emergency CABG. However, by 1998–1999, the rates of emergency CABG converged, and there was no longer a significant difference in overall CABG rates (OR 1.34, 95% CI 0.76 to 2.38; p = 0.315). On average, over the entire period of study, the MI rates were not discernibly different in women versus men (OR 1.02, 95% CI 0.85 to 1.24; p = 0.810), and there were no significant difference in rates when each period was examined separately (e.g., for 1998 to 1999, OR 1.18, 95% CI 0.84 to 1.68; p = 0.339). The average mortality rate during this period was slightly higher for women (1.21%) than for men

Table 4. Adjusted* Rates of In-Hospital Outcomes of Women and Men Undergoing a PCI in Northern New England by Era of Stenting

In-Hospital Outcome	Stent Era: Early (1994–6/95)	Stent Era: Provisional (7/95–1997)	Stent Era: Current (1998–1999)	p_{trend}
Clinical success (%)				
Women	89.03	91.45	93.45	< 0.001
Men	88.25	91.23	94.20	< 0.001
MI (%)				
Women	2.44	1.76	1.71	0.378
Men	2.18	2.09	1.36	0.009
Any CABG (%)				
Women	3.39	2.10	0.94	< 0.001
Men	3.32	1.66	0.83	< 0.001
Emergent CABG				
Women	2.20	1.54	0.60	< 0.001
Men	2.15	1.14	0.55	< 0.001
Nonemergent CABG				
Women	1.08	0.50	0.38	< 0.001
Men	1.04	0.52	0.28	< 0.001
Death (%)				
Women	1.36	1.30	1.04	0.846
Men	1.14	1.27	0.79	0.273

*See Appendix A for list for regression models.
CABG = coronary artery bypass graft surgery; MI = myocardial infarction; PCI = percutaneous coronary intervention.

(1.06%), although the difference did not reach statistical significance (OR 1.24, 95% CI 0.96 to 1.60; p = 0.096). The same was true when the analysis was confined to any period, including the more current era (OR 1.49, 95% CI 0.94 to 2.35; p = 0.086) in which the absolute difference in mortality rates was quite small (0.25%).

DISCUSSION

As the practice of PCI has evolved over the last decade, outcomes in women in Northern New England have improved, despite an ever-sicker patient population undergoing the procedure. The major changes were decreases in both the need for CABG (emergent and nonemergent) and the incidence of postprocedural MI, resulting in improved clinical success. Almost identical changes were noted for men. The most current data (1998 to 1999) show no gender-related differences in the rates of post-PCI CABG or MI. Mortality rates changed little over the second half of the decade, and there was not a statistically significant difference in mortality between women and men, even in the current era. In fact, an interaction term for gender and year was not significant for any adverse outcome.

Outcomes in women versus men. Although the average crude mortality rate for women was higher than that for men (1.52% vs. 0.89%, p < 0.001), the adjusted rate was much more comparable and not significantly different (1.21% vs. 1.06%; OR 1.24, 95% CI 0.96 to 1.60; p = 0.096). Some investigators have attributed much of the higher mortality rate seen in women after coronary revascularization to their relatively smaller size (3,8,25–27). Mechanistically, body size has been associated with vessel size (28,29) and, in turn, small vessel size with an increased likelihood of post-PCI complications (30–32). Even when corrected for body size, vessels in women may be smaller than those in men (33). When we did not adjust for BSA, postprocedural mortality differed between women (1.31%) and men (1.00%), and the difference was significant (OR 1.36, 95% CI 1.08 to 1.71; p = 0.009). Controlling for BSA reduced the mortality difference and made it statistically insignificant.

What have others reported for post-PCI outcomes in women in recent years? Mehilli et al. (34) published data on 4,264 consecutive patients who underwent PCI with stent placement at two referral centers in Germany from 1992 to 1998. The crude mortality rate at 30 days was 1.7% for women and 0.8% for men (p = 0.02). The adjusted hazard ratio at 30 days for death plus MI was 2.02 (95% CI 1.27 to 3.19). Vessel size was included in the multivariate analysis, but proved not to be a predictor of the combined 30-day outcome. The National Cardiovascular Network Registry reported outcomes of 109,708 procedures performed at 22 selected centers from 1994 to 1997 (35). The stent rate during this period was 37% for women and 40% for men. Although the unadjusted in-hospital mortality rate for women (1.8%) was higher than that for men (1.0%; p < 0.001), the adjusted OR of 1.07 (95% CI 0.92 to 1.24) was insignificant. Women did have higher rates of Q-wave MI (OR 1.25, 95% CI 1.1 to 1.4) and repeat revascularization (OR 1.13, 95% CI 1.1 to 1.2). In contrast, Watanabe and Ritchie (36) used a 1997 sample of hospital discharge abstracts to identify 118,549 patients from 21 states who underwent PCI. Regardless of whether the procedure was peri-infarction or involved a stent, women had a higher post-PCI mortality than did men, with ORs ranging from 1.30 to 1.65 (depending on the patient population). Postprocedural CABG rates were higher for women than for men in patients receiving a stent, regardless of the indication (OR 1.26 for peri-infarction; OR 1.55 for other indication), but were comparable after PCI in nonstented patients. Using another administrative data set—a national sample of 1996 Medicare data—Wennberg et al. (37) also reported increased in-hospital post-PCI mortality for women compared with men (OR 1.25; $p < 0.001$). Recent studies from several other large registries have reported only on data collected through 1994 (38–40), before the widespread availability of stents.

Temporal changes in outcomes. The decrease in CABG and MI rates that we saw paralleled the temporal growth in the use of coronary stents (Fig. 1). We suspect, as others have found (41), that the availability of stents allowed interventionists to better cope with suboptimal results and to avoid abrupt closures. In a multivariate model, stent use was associated with a decreased risk of postprocedural CABG (OR 0.31, 95% CI 0.26 to 0.37). It was not associated with a reduction, or increase, in the clinical postprocedural MI rate (OR 1.12, 95% CI 0.97 to 1.29), as we defined it.

The availability of coronary stents may not be the only factor responsible for the temporal decrease in adverse outcomes. Improvements in guiding catheters, wires, and balloon catheters may have increased the likelihood of procedural success by facilitating the crossing of lesions and/or their engagement. The increased use of a rotational atherectomy device may have resulted in more success with calcified and fibrotic lesions. The physicians' cumulative experience with PCI increased over the study period and may have led to improved clinical judgment in patient selection and procedural decisions. Recent trials (42,43) have found the routine use of GP IIb/IIIa inhibitors improved post-PCI outcomes, regardless of gender (44). It is unlikely that the use of GP IIb/IIIa inhibitors contributed much to our findings. The use of these agents was largely confined to 1998 to 1999, which antedates the gradual decline in CABG we observed, and the presence of these agents was actually associated with an increased risk of MI in these data, suggesting a possible selection bias in their use.

It is not clear why mortality rates did not fall over time. Decreasing the rates of CABG and MI might be expected to lead to a reduction in postprocedural mortality. However, <14% of deaths occurred after CABG or MI, and the case-fatality rate remained relatively constant over time. There was an increase over time in the complexity of the lesions being attempted. Although this could be a consequence of coding "creep," it might also mean that physicians were attempting more complex lesions and that, despite the availability of stents and adjuvant therapy, patients were getting into trouble. In previous work (45), we showed that only half of all deaths after PCI could, in some way, be tied to a technical complication of the procedure. The other half were due to preexisting acute cardiac disease, progression of chronic cardiac disease, or noncardiac disease. Welty et al. (46) also reported a high incidence of noncardiac death after PCI, which, interestingly, was 16-fold greater in women than in men. Even if mortality due to technical complications was falling, intervening in a higher percentage of patients with disease processes that directly relate to death could obscure any decreasing procedure-related mortality, resulting in no apparent change in death rates over time. Although we can control for the presence of many comorbid conditions that increase the risk of dying, we cannot necessarily control for their severity. The same could be said of our measures of patient acuity, though repeating analyses after excluding patients requiring an emergent procedure did not change our results. Even a large study could be underpowered to detect a change in mortality rates. This is unlikely in our study, because when comparing the first half of the study period to the latter, we had 95% power to detect a 50% decrease in mortality rates for women, with an alpha level of 0.05.

Other registries have also found little change in mortality over time. The National Cardiovascular Network PCI data base (47) reported an overall mortality rate of 1.3% in 1994 through 1997, with no significant change in mortality over the study period. The National Heart, Lung, and Blood Institute's Dynamic Registry of PCI reported no change in mortality rates between 1985 to 1986 (1.9%) and 1997 to 1998 (1.4%) (48). However, using 1996 to 1998 data from the Society for Cardiac Angiography and Interventions Registry, Kimmel et al. (41) reported an overall mortality rate of 0.5%—half the rate seen in Northern New England. In that analysis, patients undergoing a graft PCI or in whom a device was used were removed from the analysis. Removing these patients from our analysis still resulted in an overall mortality rate of ~1%. Data from the Society Registry were not validated, and it is possible that under-reporting of adverse events explains the lower death rate in their study cohort.

Study limitations. There are several limitations to our study. We report on a regional experience in the Northeast, which has a more conservative practice pattern than other areas of the country (49), possibly limiting the generalizability of our results. However, the characteristics of our patients and our rate of stenting are comparable to other reports (30,48,49). Perhaps more relevant to the issue of generalizability is the fact that all our operators and all our institutions in Northern New England met criteria for being "high volume," which is not true of other regions of the country (50). As we (51,52) and others (53) have reported, there is an inverse relationship between volume and PCI outcomes, so our results in Northern New England may be better than can be expected elsewhere. Myocardial infarction was not a validated outcome, and it is possible that our point estimates of this event may be too conservative. However, in another study of data collected in the early 1990s (54), a chart-based review of our data demonstrated no under-reporting of MIs, as we defined them. We cannot comment on gender-related or temporal changes in asymptomatic elevations in cardiac enzymes, as this information was not collected. Finally, as with any observational study, uncontrolled confounding could have affected our analysis of differences in outcomes between women and men or of changing outcomes over time, although we did use standard patient and disease characteristics to try and eliminate this possibility (55).

Conclusions. There has been concern in the cardiology community that cardiac care for women has been inferior to that for men. In this study, we demonstrated that as the practice of PCI has evolved over the mid to late 1990s, outcomes for women have improved. Women do present somewhat differently than do men, and we cannot comment on whether this relates to the biology of the disease or to bias in recognizing the disease, or both. Once the decision is made to proceed with PCI, outcomes for women are good and comparable to those in men after adjusting for baseline differences in presentation and co-morbidities. Of particular importance is the recognition that because women, on average, are smaller than men and because body size relates to procedural outcome, women, on average, will have a slightly higher adverse event rate than will men. However, once we adjust for body size, the event rates are comparable. Based on these insights, PCI should be considered a viable option for women. In addition, regardless of gender, interventionists should pay particular attention to procedural details such as sheath size, choice of device and its size, dosing of drugs, and access site care in all patients with a small BSA. The future will continue to bring innovations in the practice of percutaneous coronary revascularization, and observational studies such as ours will continue to be needed so that patients and practitioners are provided with the best of information to make their medical decisions.

Reprint requests and correspondence: Dr. David J. Malenka, Section of Cardiology, Dartmouth-Hitchcock Medical Center, Lebanon, New Hampshire 03756. E-mail: david.malenka@hitchcock.org.

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APPENDIX

Logistic Regression Models for Each Outcome Variable

1. In-hospital death: age, BSA, creatinine >2 mg/dl, ejection fraction, LVEDP, indication, emergency priority, thrombolysis, preprocedural intra-aortic balloon pump, preprocedural intravenous nitroglycerin, and ACC type C lesion.
2. CABG: age, BSA, DM, previous MI, previous PCI, previous CABG, emergency priority, number of diseased coronary arteries, PCI of the proximal left anterior descending coronary artery, and ACC type B2 or C lesion.
3. Emergency CABG: age, BSA, DM, previous CABG, previous PCI, emergency priority, number of diseased coronary arteries, proximal left anterior coronary artery lesion, and ACC type C lesion.
4. Nonemergency CABG: BSA, DM, previous MI, previous PCI, indication, number of diseased coronary arteries, preprocedural heparin, and ACC type B1, B2, or C lesion.
5. MI: BSA, LVEDP, preprocedural heparin, number of diseased coronary arteries, graft PCI, and ACC type B1, B2, or C lesion.
6. Clinical success: age, BSA, DM, creatinine >2 mg/dl, indication, emergent priority, number of diseased coronary arteries, LVEDP, graft PCI, and ACC type B1, B2, or C lesion.